TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
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STAKEHOLDERS MEETING WITH)
NATIONAL GRAIN and FEED)
ASSOCIATION)
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UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
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NATIONAL GRAIN and FEED)
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Training Room 1
4700 River Road
Riverdale, MD

Day, Friday
Date February 27, 2004

The parties met, pursuant to the notice, at 3:17 p.m.

BEFORE: MS. CINDY SMITH
Deputy Administrator

APPEARANCES:

For the U.S. DEPARTMENT OF AGRICULTURE:

REBECCA BECH, Assistant Deputy Administrator
JOHN TURNER
NEIL HOFFMAN
MICHAEL WACH
SUSAN KOEHLER

Meeting with: National Grain and Feed Association
THOMAS C. O'CONNOR, Director of Technical Services

PARTICIPANTS:

LEVIS HANDLEY
ROBYN ROSE
MICHAEL BLANCHETTE
CRAIG ROSELAND
MEGHAN THOMAS
HALLIE PICKHARD
JIM WHITE
LAURA BARTLEY

P R O C E E D I N G S

(3:17 p.m.)

MS. SMITH: Welcome to our Stakeholder Discussion series.

MR. O'CONNOR: Glad to be here.

MS. SMITH: Thank you. We want to thank you for taking time from your busy schedule to join us today. We really look forward to your participation in this meeting as well as hearing your thoughts which you will share with us today.

The purpose of these briefings are two fold. First, to give us an opportunity to share information about our plans to develop an EIS and amend our biotechnology plant regulations. The second is to give us an opportunity to gather diverse and informative input, which will be supportive for factual and effective decision making on our part as we update our regulations.

We have here BRS members of our management team as well as members of our staff; and, when available, other key Agency personnel involved in supporting this effort who will be joining us from time to time. I do want to mention two key individuals who have now been dedicated to this effort on a full-time basis. One who you are probably

familiar with is Dr. John Turner. John is a key member os our leadership team here at BRS; and I am pleased to say that he is now leading our effort on a full-time basis, both the completion of our EIS and the development of our new regs.

Another individual, who is probably a new face that you are not familiar with, is Dr. Michael Wach. Michael is a recent BRS hire as an environmental protection specialist within our Environmental and Ecological Analysis Unit, which we announced some time ago. That is the unit that Susan Koehler heads up. In addition to possessing a Ph.D. and an environmental law J.D., Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving NEPA, the Clear Air Act, the Clean Water Act and other environmental statutes.

At this point, I am going to turn this over to John. John will provide you with some additional background information in terms of how we plan to proceed, and then we will open it up to any kind of conversation that you would like to have with us, whether you want to read something into the record, or just have a give-and-take on the notice.

MR. TURNER: Thank you. As you probably

know, we have been in discussions with EPA, FDA, and the White House on biotechnology regulations. While we have concluded that coordinated framework has provided an appropriate scientific risk-based regulatory system, we also found that the Plant Protection Act of 2000 seems to provide a unique opportunity for APHIS to revise its regulations and potentially to expand our authority while leveraging the expertise gained through our history of regulation; and that potential revisions could position us for future advancements of the technology.

We also concluded those discussions with a very general agreement on how the bio-tech regulatory approach would evolve. But still there is much opportunity, since it is early in the process for public and stakeholder input, as we move forward and develop the specifics of our regulatory enhancements. Given this, that is why we are having these meetings to hear your thoughts.

This is primarily our purpose as well as to have an informal give-and-take of ideas. It is a unique time in which we can speak very freely and openly and share ideas because we are not yet in the formal rule-making phase of the process.

On a different note, our discussions are

being professionally transcribed for two primary reasons. First, an accurate record of our discussions will facilitate our ability to capture and refer to your input; and secondly, for purposes of transparency and fairness to all stakeholders, we will be making available, as part of the public record and potentially on our Web site, documentation of all of our stakeholder discussions so that the public and other stakeholders will benefit from the discussions we had with each of the other stakeholders during the week.

I want to emphasize that while we are happy to share information about the process, because it is evolving, the input we get from you and the other stakeholders and the public will influence our thinking as time goes on. In addition, we will, of course, get input from within the Agency from our APHIS administrator and the undersecretary and our Office of General Counsel and from the secretary. These will all shape our future direction.

While we may have a lively discussion about some aspect of it today, it is just good to keep in mind that it is an evolving process. Finally, since it is an evolving process and we don't know exactly what the final regulation will look like, it is

important to emphasize the priority areas of emphasis that will shape that regulation, and these we are sure of. There will be rigorous regulation, which thoroughly and appropriately and ensures safety, and is supported by strong compliance and enforcement.

Transparency of the regulatory process and regulatory decision making to stakeholders and the public is critical to public confidence. We will have a science-based system, which insures that the best science is used to support regulatory decision making in order to assure safety. There must be communication, coordination and collaboration with a full range of stakeholders.

Finally, international leadership. We need to insure that intentional bio-tech standards are science based. We want to support international capacity building; and we recognize that it is important to consider international implications of any policy of regulatory decisions that we make here domestically.

With that, we are ready to start the discussions. If you could simply state your name before you start, then we can go wherever you like to hear your comments.

MR. O'CONNOR: Sure. My name is Thomas C.

O'Connor. I am the director of technical services with the National Grain and Feed Association, located in Washington, D.C.

First of all, let me say that I appreciate the opportunity to be here this afternoon. I don't have a prepared statement to read into the record, but I think I would be very much interested in having some dialogue with staff here to better understand some of the potential changes that you have in mind.

We have sent this out to our respective committees that will be helping us develop our policy recommendations back to the Agency. But franking, in setting it out to them, there were a lot of questions we had as to what you meant, what this could mean, and so on and so forth?

So, if it is okay with you, I would kind like to walk through this a little bit with you.

MR. TURNER: Sure.

MR. O'CONNOR: And just pose some questions and give my initial reactions; and any reactions, of course, that I would give would be just simply preliminary at this point.

MR. TURNER: Sure.

MR. O'CONNOR: We have to, of course, run this by our committees that develop policies. But I

think from this perspective, it would be helpful for me to get some better understanding of what you are trying to achieve here and what some of the policy implications are, specifically with respect to some of the environmental issues that you mention here.

So let me just start at the beginning. You noted a couple of broad alternatives. One is take no action. You go in here and you mention that the alternative contemplates no change in the existing regulations. The existing regulations pose a potential plant-test risk. However, when I read the definition of a plant test, it was a protozoan or a non-eating animal present in plant bacteria and so on.

I didn't understand what you meant by that? Is that a specific type of genetic crop that is different than the ones we have today? How should I interpret that?

MR. TURNER: All of the ones that we have today, that is the standard by which we evaluate them: Whether they post a plant-pest risk? So even though you didn't see plant listed there, it is whether they can pose a plant-pest risk in some way similar to the way that known plant pests do?

MR. O'CONNOR: Okay.

MR. TURNER: That the status quo. That is

how we evaluate all genetically engineered organisms today. We evaluate them to their potential to pose that type of risk.

MR. O'CONNOR: Okay. When I read that and I went back to the definition, I was wondering: Are we talking about two different things here? So that clarified that. Thank you very much.

Also, I guess if you don't go that route, then there is a number of, I think it is 9 or 10, options that you have on the table that could be changes. One of which is, I guess, evaluate or broaden your regulatory scope to include genetically engineered plants that may pose a noxious-weed risk, and genetically engineered organisms that may be used as a biological-control agent.

I guess that I am little surprised that you weren't doing that now. But maybe you could educate me a little bit more about why you don't regulate noxious weeds and these other things now and what benefits we gain by doing it if we expanded this?

MS. SMITH: Our current regulations are just based on the potential to be a plant-pest risk. In looking at these two other authorities, one thing that it would allow us to do is: If you look at the definition in the Plant Protection Act of 2000 of a

noxious weed, we would be in a position then to evaluate anything that came into the system, any genetically engineered plant, to see if it posed a noxious-weed risk.

If you look at the definition of noxious weed in the Plant Protection Act of 2000, it is really very broad. The definition is essentially along the lines of: any plant or plant product that poses a risk to, or is harmful to, agriculture, the livestock or crops, navigation, irrigation, transportation, human health or the environment.

What it, for example, moving to adopting a Noxious Weed Authority as part of the basis for our regulations, would allow us to do is to look at things that come into the system, genetically engineered plants or these other organisms. Look at them on a much broader basis in terms of our review. Now we are only primarily looking at plant health. But at the point at which we would move to adopting a Noxious Weed Authority, then we could look at the food safety, the impact to humans and the broader aspects of environmental safety.

So our review would be much broader.

MR. O'CONNOR: Broader. Would this at all be in conflict, or raise issues with FDA that may also

be looking at human health and animal-health issues as well?

MS. SMITH: Yes. That is a very valid question. No, we don't believe that it would. Part of what we went through in the process, in the interagency process with FDA and EPA and the White House, was in looking at these potential changes and talking about how the agencies would work together and making sure that we are not creating redundant regulations, but, in fact, just strengthening the coordination that goes on between these agencies already.

MR. O'CONNOR: I think my own initial reaction to that proposal is we probably would encourage that. But, again, you would have to see how we come about that. That is interesting. I didn't realize that you guys didn't do that now. It would seem that a noxious weed would be something that could impact on the environment, but I guess you are only regulating from the health of the plant, aren't you.

At least before, when you talked about plant-pest risk, that is something that would negatively impact on the plant. Is that what you are telling me, how you were viewing these things before?

MR. TURNER: Yes, a plant pest is in the

organism. They have copies of this outside at the registration. So a plant pest is any organism that can do harm to a plant or a plant product. Then, because federal actions are subject to NEPA, the National Environmental Policy Act, under NEPA, we looked at a broader range of environmental issues with respect to that.

MR. O'CONNOR: All right. That is interesting.

MR. TURNER: Another clarification: APHIS, does, of course, regulate noxious weeds under its Noxious Weed --

MR. O'CONNOR: But it's not as a bio-tech.

MR. TURNER: Yes, we haven't regulated bio-tech, so there is some communication to take place. If you look at the definition of a noxious weed, it is very broad. It is much broader than --

MR. O'CONNOR: Yes, we are familiar with it in the hytosanitary arena. Absolutely, we deal with that not only as an import, but as an export as well, sometimes, not based on sound science in other countries.

You mention here in No. 2 that you define specific risk-based categories in field testings. As I go down through here, it talks about pharmaceutical

and industrial crops not intended for food or feed. The focus on this is environmental factors. Then it goes on to say: Should certain low-risk categories be considered for exemption for permitting requirements?

The issue of pharmaceutical and industrial crops raises a real problem for us, should the Agency move in the direction of reducing its regulatory requirements for such crops. Then the possibility of the potential that they could somehow make their way into the general commodities stream, in our view, probably increases, or at least increases our concern that such can happen.

While, I think the bio-tech industry itself has been moving in the direction of trying to get approvals for many of these crops, that they were introducing agronomic traits approved in some of our major export markets, it is not clear why they would take the same actions for pharmaceutical and industrial crops?

So, if they do move into the food and feed supply, then we would be very concerned that we would be facing, in some of our major export markets, the same thing that we faced with Starlink, which is a zero tolerance. Unless we can be convinced that somehow this can be avoided, I think that we would be

very reluctant to endorse reduced permitting requirements. Even though the crop itself may not impose an environmental risk per se for those kinds of crops, we are going to lack that approval in the overseas' markets.

MS. SMITH: I appreciate that comments. One clarification just so that you know for the purpose of your comments. In this document when we refer to the environment, it is the full human environment. It is not just the environmental factors that we want raised in terms of comments, but also human health factors. It is a very broad definition of environment.

MR. TURNER: In No. 2, that is where we talk about the different categories: the low risk, the medium risk and then the high risk when we talk about pharmaceuticals. That question was meant to apply to all of them should certain low-risk ones be exempt, just the pharmaceuticals and industrials.

MR. O'CONNOR: Okay.

MR. TURNER: But certainly your comment is still just as appropriate. If you think that there is a certain category where there should be no exemption, then it would be helpful in the regulatory --

MR. O'CONNOR: Our concern, John, is not one that could be addressed through science per se. It is

really a commercial issue for us and you would raise a whole host of concerns, I think, within the exporting industry, if we went down that path. If we just got the passage of protocol, which you can require the identification of crops and so on.

It just raises -- and we talked to Cindy about this and probably some of your other staff as well in the past. But that would be our major issue there. Again, it wouldn't be a science-based one as much as it would be a commercial one. So any efforts along those lines would have to -- certainly, we would like you to be cognizant of that concern as well.

The next one deals with the volume of regulatory flexibility for the commercialization of certain genetically engineered organisms while continuing in some cases to regulate that organism based on minor unresolved risks.

What do you mean by that?

MS. SMITH: Yes, that is not real clear, I think, when you read that is: We have a very effective deregulation process that has worked well for a number of years. What we are trying to do, though, as we look down the road and try to anticipate the technology and understand that there are things that we will need to regulate that we don't foresee now, we

are trying to build additional flexibility into the deregulation system.

So what we would likely consider is an evolution of our deregulation system. It may move to more of an approval system, in which we are approving something for confined release, or approving it for unconditional release; or, alternatively, approving it with some conditions.

The flexibility that we are looking at, and this again is at the early stages and we are inviting comments for us to consider, would be: Is there something that we could foresee that would come to the system that would overall be largely safe? But there may be some science-based minor unresolved risk that, allowing this to go forward in terms of an approval, but may be put in place of the requirement to gather some additional information, monitor for some data, which may not be available to us until it is approved.

Would that be a useful flexibility to build into the system? We may want to approve something with the restriction that we will gather certain information over the same five-year period. Then, at the end of that five-year period, that information will address that minor unresolved risk. So, at that point, we can approve it unconditionally.

Another thing that we are looking at is: Whether there should be the types of restrictions on some approvals which might be in a situation of a given crop that is an annual in one climate and a perennial in another climate? Is that something that we want to try to address? Again, this is really in the early stages of thinking, but we are just trying to build in some flexibility to the system to anticipate situations that we are not currently aware of.

MR. O'CONNOR: Sure.

MS. SMITH: What we do envision, though, is that with the things that we are seeing now, this would not be necessary. And most of the things that we would envision that would come to us, maybe 98 percent of the things, we wouldn't need to exercise this. We are just trying to build in some flexibility for those few cases that we want to just allow ourselves to do a little bit more than we can do in our current deregulation system.

MR. O'CONNOR: Sure. I am not opposed to flexibility. I think you need to have rules that will be able to deal with things in the future. Again, this is our initial reaction to this. The only concern that I would have with something like that is,

again, as we try to get crops approved in foreign markets, they often look to the U.S. and say: Have you approved it? And if there is a condition on that crop, does that inhibit some foreign country from approving it? Then, again, if it is in our system, it raises all sorts of zero-tolerance problems and so on.

Additionally, if that restriction is related to some environmental concern that you have unresolved at this point, again, we have the bio-safety protocol, which is going into effect, which is designed to prevent the adverse affects on bio-diversity from living modified organisms, which are food crops as well.

So that might be something that you would have to think about as you begin formulating these plans.

MR. WACH: Could I ask you to express your opinion. Would it be better, in your opinion, to not impose the condition, but simply have the material under regulation for an additional year or two? Or to have this conditional deregulation, but you did collect data for two years?

MR. O'CONNOR: My opinion on this is that it would be better to have it under regulation, so that any chance of it getting into the general commodities

stream is further minimized, rather than giving conditional deregulation where perhaps the chances of it getting out are increased.

Again, we are just overly sensitized perhaps from the Starlink situation, if you remember that or not. But even though today, we have extremely low levels of Starlink in our system, it is .0001 percent or whatever. It is still a problem for us in some of our export markets. So, even low levels of the materials, can present trade barriers. True or false?

MR. WACH: So a foreign market would be happier to see us hold onto it under regulation for two more years, for example, to show our extra care with it. Then, for instance, let it go with conditions for that same amount of time.

MR. O'CONNOR: Yes, we would be concerned frankly if there was a perception that we are not regulating this partially deregulated crop as rigorously as we should. But simply because it is not approved in some foreign nation, that they may, at that point, begin to require exporters to test for it to make sure that it is not there. That just adds cost and so on.

MS. SMITH: Thank you.

MR. O'CONNOR: No. 4, I guess my answer to

this was: yes, should not and no affect. Are there changes that should be considered relative to the environmental review of, and permanent conditions for genetically engineered plants produced for pharmaceutical and industrial compounds? Should the review process, permit conditions and the requirements for non-food crops used for production of pharmaceuticals and industrials, differ from those for food crops?

I guess my reaction to that is: yes. They should be. Why wouldn't they be? I just pose it back to you.

MS. SMITH: I think the real point we are getting to here is: If we move to the Noxious Weed Authority, then that will give us the authority to look at food safety; whereas, now, that strictly falls within the FDA. So, given that, should that shape the regulatory requirements that we have put in place for pharmaceuticals and industrials?

If something doesn't have food-safety review by the FDA, should it be more confined than something that does?

MR. O'CONNOR: Sure. I know because that is the next question and I understand where that question is coming from. We have had this discussion in the

past, not only with you Cindy, but also internally with some of our committee members who, by the way, represent some of the major box-set companies.

While we understand that some pharmaceutical crops might even be considered GRAS, our concern is that if it gets out into the food -- just as I had it in my earlier comments. If it gets out into the general commodity stream and it is not approved in some major export market, even though it is GRAS, we still face that zero tolerance overseas.

We just can't get around that. That is just a problem that we face and unless the bio-tech industry itself is willing to get approvals for that crop in our major export markets, which is going to add costs in actually doing it, I don't see how we can get around it frankly.

MR. HOFFMAN: Now, it is possible that you could have marketing of a product in the United States and not marketing elsewhere. How would you feel about that?

MR. O'CONNOR: Well, if its in a non-food crops. Like you grew it in tobacco, for example, that is an entirely different issue than if it is produced in corn, which has been in a factory, if you will, for pharmaceuticals in the past. Whether it will be in

the future, I don't know. But for those types of crops that we use in the general commodities stream of corn, soy beans, wheat, sorghum, oats, barley, those kinds of things. If they were used, I think probably the only ones that I have ever actually seen that would be credible would be corn. But if the other ones were used as well, then we would certainly not endorse a food-safety certificate as being permission, and then to just plant it anywhere and let it bleed into the system.

Now, if there are other crops out there that you have in mind, I think that is fine. So maybe perhaps a conditional approach on this might be more appropriate than one that is more broad.

MS. SMITH: Thank you.

MR. O'CONNOR: Okay. That probably addresses the second. Then the last one, which is: How should the lack of a completed food-safety review affect requirements for these types of plants?

Again, from my perspective, for the general commodity crops, whether it has or it has not a food-safety review is really not a relevant issue for us. The relevant issue for us is: What is it going to do to our overseas' markets? We export about 20 percent of our corn, a third of our soy beans and close to

half of our wheat. So if we endanger any of those markets, it can have a pretty devastating impact on the price of grain in the United States, as well as the health of our system in pharmacy.

MS. SMITH: So, in our case, if we are regulating based on science and risk, even when there is not the science to show that there would be a risk with a certain pharm or industrial crop, the dilemma for us is the fact that another country would not recognize that lack of a risk.

MR. O'CONNOR: That is correct.

MS. SMITH: So it still creates a risk for you in terms of --

MR. O'CONNOR: A commercial risk, yes, exactly. I understand the science behind it and so on. I want to emphasize that we believe very strongly that we should have science-based regulations at PATH, but we just can't get around the fact that the commercial side of this also plays an important role for us.

MS. SMITH: It is a very interesting Catch-22.

MR. O'CONNOR: Yes.

MR. WACH: Do you see anything changing over time? I don't know. Are we going uphill in terms of

negative attitudes towards these products? Are we at the maximum level of concern? For food in the foreign markets, you see the --

MR. O'CONNOR: I would like to believe that we are heading in the right direction. I just had a meeting with some of your colleagues over at FAS. We talked about this notion of synchronous approvals, i.e., we have approvals here in the United States that are lagging throughout the world; and how that problem is probably going to multiply as we get more and more -- just simply the agronomic-trait crops in our system and we have a mounting challenge on how we deal with that?

And how do yo deal with it? There is no really ready answer to it, so I would say, at least in the short term, that the problem is probably going to stay with us and perhaps get worse.

MS. SMITH: It is very difficult.

MR. O'CONNOR: I wish you had a better answer.

MR. WACH: No, no --

MR. O'CONNOR: Believe me, we would love to see it solved tomorrow. In No. 5, noxious weed, it says: basically for APHIS considering the regulation of non-viable plant material.

I am not exactly sure what you meant: non-viable plant material?

MS. SMITH: We are not real certain on what we mean by that either. We are just sensitizing stakeholders and the public to the fact that, in the Plant Pest Act, we are limited to regulating only viable-plant material.

If we move to using the Noxious Weed Authority, the definition of the noxious weed used for noxious weed includes plant and plant products. So it could also include non-viable plant materials. It is an area we have not regulated in the past, so we are just kind of putting that out there to say: Is this an area that we should consider regulating? If so, what should be the considerations?

MR. O'CONNOR: What do you think non-viable plant material would be? What would you visualize that as being?

MS. SMITH: It could be corn stocks that don't have any corn seed that are no longer growing.

MR. O'CONNOR: Okay.

MS. SMITH: Like laying in a field, for example.

MR. O'CONNOR: Okay.

MS. SMITH: That might be one example.

MR. O'CONNOR: Now, these would only be for crops that present a noxious-weed risk?

MS. SMITH: Well, if we are regulating under the Noxious Weed Authority, then we can leverage that definition and we would be looking at all of the factors related to that definition. It wouldn't be that we are saying that they necessarily constitute a noxious-weed risk, but that we are going to evaluate plants and plant products, or parts of plants, to make sure that they don't pose harm to agriculture or human health and all those things identified in the deposition.

MR. O'CONNOR: Sure.

MR. TURNER: So, you know, as you read it -- that same one, it says: If so, if you think we should regulate it and what cases and you can think back to categories and maybe you don't know if we should at all. If so, maybe there are certain cases --

MR. O'CONNOR: Well, I don't know whether you should or not, to be honest with you. I am enough of a scientist to not say that this is a problem or not. I am just curious as to what you had in mind. Okay.

MS. SMITH: We're not sure what we had in mind. One example that another group mentioned

earlier today was: Maybe you want to regulate non-viable material if it's -- you wouldn't do it for your traditional food and feed crop that you are regulating, but maybe for pharmaceuticals and industrials, --

MR. O'CONNOR: Sure.

MS. SMITH: -- maybe for those that pose a risk, maybe you do.

MR. O'CONNOR: Yes.

MS. SMITH: We are not saying that that is what we are considering. That is just another example that was thrown out by --

MR. O'CONNOR: So, the viable material might be, as you mentioned, some of the plant material and some of it may be left in the field. I have to think about that. I guess my initial reaction was: Yes, it probably should. But I think we would want to take one under a little bit more -- there may not even be an answer for it, frankly --

MS. SMITH: And that is probably --

MR. O'CONNOR: -- even if they could give you a good response. In No. 6, let's see: This deals with a producer I guess wanting to extract pharmaceutical and industrial compounds under confinement conditions with government oversight

rather than use the approved process for unconfined release.

Maybe I just didn't understand the question, but I didn't think that you could have unconfined release of pharmaceutical and industrial crops.

MS. SMITH: Let us clarify. We are looking at two avenues for growing pharmaceuticals and industrials under the new regulation. One is that if pharmaceuticals and industrials can meet the same safety criteria for deregulation, they may be able to qualify for deregulation, but they would have to meet those safety criteria.

The second -- given that a number of those would not meet that criteria and given that we are hearing, pretty consistently, from a number of groups that even if a pharmaceutical or industrial could meet that criteria, there is a lot of interest in maintaining them under government oversight.

What we are looking at is: Is there a separate mechanism that we want to establish, really tailor made for the long-term production of pharmaceuticals and industrials from crop plants. So, for example, what we are looking at there is -- currently, a company submits an application to consider what they are going to grow this year, and

then we do an analysis on that application, and then we give them permission to grow for that year.

When companies are to the point where they are ready to commercialize, theoretically, they are going to have a longer-term game plan in mind where they are maybe going to do the same growth every year for five years because they have a company that they are going to extract something from and sell it to.

So if there is a longer-term game plan, is it more appropriate for us to look at what that long-term game plan is?

MR. O'CONNOR: Sure.

MS. SMITH: Do a full evaluation of that longer plan up front and then, rather than have a one year, year-by-year permit, we will have a longer-term approach that would do a full evaluation up front and then with every year, additional data is submitted that may come as a result of that last year's growth.

Another facet of that that we are looking at is: We really would like to have something more transparent for pharmaceuticals and industrials. Confidential business information, of course, is something that we have to honor and will require not to share it. But, at the same time, we are thinking that for pharmaceuticals and industrials, it is more

important than ever to have a mechanism where the public knows and stakeholders know what kinds of things are being grown, as well as what the safeguards are that are put in place to assure that those are staying confined.

So, in this new mechanism, we may have an additional requirement for a company. Let's say, they give us a one-page summary that we can post on our Web site that your average member of the public can understand, that tells the public what it is they are growing without violating confidential business information, as well as explains how the safeguards are put into place.

We are just kind of thinking about: What is unique about long-term commercialization? Long-term growth to commercialize pharmaceuticals and industrials from crop plants, how should our government oversight of that evolve with it together to address what is specific to that?

MR. O'CONNOR: Sure. That probably answered that. Again, the commercialization of pharmaceuticals and industrials just raises a whole host of issues with us. I don't know. I'm sorry. I should place it more on the commercial side.

MS. SMITH: And we would appreciate the

extent to which you can delineate those requirements?

MR. O'CONNOR: Sure. And we will.

MR. TURNER: This option is commercialization, but it is maintaining strict --

MR. O'CONNOR: Strict regulations, yes, which we would support.

MR. TURNER: A new mechanism that is still an oversight.

MR. O'CONNOR: This No. 7 is an issue that is near and dear to our hearts, which is this issue of: adventitious presence.

It is kind of a difficult issue for us because, on one hand, we would like to see the government have a policy on adventitious presence because we believe that the lack of such a policy on the part of the U.S. government inhibits the development of one on a international scale.

Countries will often look at states and say: Well, we told them that we could have this small level of these crops and our danger shouldn't -- our shipments, you should not deregulate that. But we don't have a similar policy in the United States. So I think: Yes, we broadly agree that you should have a policy on adventitious presence. But, at the same time, we run into the simultaneous problem that if we

have such a policy and we do allow some of these "unapproved crops" to bleed into the general commodity stream, we put our exports at risk again, as I mentioned before, because we face a zero-tolerance policy overseas.

So we are going to have to give this one a lot of thought, frankly, in our response back to you to make sure that we carefully word it and give you the best advice that we can from our perspective. But that is our difficulty with that specific issue.

MS. SMITH: We are sensitive to that and that is why we really look forward to seeing where you come out on it. What kind of suggestions you have for us to consider?

MR. O'CONNOR: I will just give you an aside. We belong to a group called: The International Grain Trade Coalition, which has been following developments in the various stages of protocol for three or four years now. We have been encouraging the parties to the protocol to adopt an adventitious-presence policy for bio-tech and commodity crops.

I will give you a good example where this could come into play. We do not have any bio-tech wheat in the United States but we do have bio-tech corn and soy beans. But, in the commodity systems,

commingling is common, so it is likely that you will have some small level of bio-tech corn and soybeans and non-bio-tech-like wheat. So we would like to see some adventitious-presence policy that would permit that and not ding the exporter should they want to ship a non-bio-tech product oversees. In this case: wheat.

We don't think that made the cut. It caught on poorly. They just had their first meeting. So, even on an international scale where we are seeing resistance to that notion of adventitious presence, that further complicates I think your job in terms of what policies you should have as well.

MR. TURNER: It's difficult to know.

MR. O'CONNOR: Yes.

MR. TURNER: That is a different kind of AP. If it is a regulated product, it is just GM. If it is a non-regulated product, it's just GM and non-GM; and it is not regulated, then we can't regulate that.

MR. O'CONNOR: I understand where you are coming from and I think we would be sympathetic to the notion, but just be aware that we have this other problem on our hands.

MR. TURNER: Absolutely.

MS. SMITH: Right.

MR. TURNER: That is one of the more complex issues --

MR. O'CONNOR: The next one, too: Should APHIS provide expedited review or exemption from review of certain low-risk genetically engineered commodities intended for importation that have received all necessary regulatory approvals in their country of origin, and are not intended for propagation in the United States?

I think that that would be a good thing. Again, this is my initial reaction to it because we would like to see the same thing overseas for our crops as well. So, presuming that you are talking about approval that is based on a good, rigid science-based regulatory system similar to the United States, I think that would be good thing to have happen.

Because, again, we would like to see some reciprocity on the part of overseas countries that do exactly the same thing with U.S. crops. Or perhaps if the U.S. moved in that direction, it would give us some leverage with some of our overseas customers to say: Well, we're doing it to yours. Why can't you do it for ours?

I guess my initial reaction is that is probably a good thing.

MS. SMITH: I heard you say, assuming it is based on a regulatory system in their country that is --

MR. O'CONNOR: Science based, yes. Certainly, we would want to make sure that if you are looking at giving them approval, it has to be based on something similar to what we do here in the United States.

MS. KOEHLER: May I ask?

MR. O'CONNOR: Yes?

MS. KOEHLER: Do you have any comments on the second part of that question: What are the environmental considerations that should be applied to the determinations of any such allowances? Do you have any specific comments on that?

MR. O'CONNOR: Well, again, you are interpreting this rather broadly. I always think, from our perspective, that we are talking about general commodity crops. If you have something else in mind, that is not where I am coming from.

So if you are talking about someone that has a new variety of bio-tech corn that is resistant to whatever and we liked it and we were short of corn this year and we wanted to bring it to the United States, and it was approved for food, feed and those

kinds of things and it wasn't going to present an environmental risk in the sense to some damage to the bio-diversity or something in the United States, I assume that is what you would be talking about, yes. That is kind of what I am referring to.

Did I answer your question?

MS. KOEHLER: Yes.

MR. O'CONNOR: Okay. I didn't know what the next thing was. I am not even sure that I can pronounce it. It is a genetically engineered something for interstate movement. What is that?

MR. TURNER: At present, that is sort of the white lab rat of plant research. It is called: a arabidopsis.

MR. O'CONNOR: Okay.

MR. TURNER: At present, there is exemption for that; and for anything else that is genetically engineered, you have to get an interstate movement permit. For that one, you don't. And you were merely asking a question: Are there some other plants that we know enough about that are still at risk that we also exempt from the interstate movement permit, not the other regulatory things, not planting it outside?

MR. O'CONNOR: Sure.

MR. TURNER: That is the question.

MR. O'CONNOR: I had a big question mark and I wasn't sure what that was. I will have to give it some thought and get back to you.

That really kind of covers my issues and my questions.

MS. SMITH: Okay.

MR. O'CONNOR: If you have any specific additional questions? If we have half an hour, I would be happy to sit here and chat with you about them.

MS. SMITH: I would like to go back to No. 8. So what we were talking about and your response was that you thought it might be a good thing is were the commodity to be imported that we could essentially recognize another country's system, if it is not intended for purposes of propagation, so that would mean -- would you also include the idea that if it is not intended for propagation? But what if it is a commodity that certainly could be used, like potatoes?

MR. O'CONNOR: Yes.

MS. SMITH: Would you still want us to consider exemption for all kinds of commodities, or only those commodities that wouldn't run the risk --

MR. O'CONNOR: I'll be selfish here. If I was a producer, I might have a different answer. But

I would say, from our interests, that getting mutual recognition shall we say for crops that are not for propagative purposes but come into the country that can be used for feed, whether it be food or soybeans or for further process, or something like that, would be our major interest.

We believe that there is going to a growing amount of regulatory schemes around the world for a number of reasons, bio-tech virtually being one of them. But there are other reasons as well.

And I mentioned this notion of a synchronous approval earlier in our discussions about whether this problem is going to get worse or better? The notion of lack of, or just lag of approvals, could potentially be addressed if we could get some system in place where it is approved in the United States. It is approved in these countries over here or if it is approved over there and the United States accepts it and so on and so forth, and we all had mutual confidence that the approval process was rigorous and science based.

So that is where I would be coming from on that one. If you just did it from the food, feed and further processing side of it, that would probably satisfy our needs.

MS. SMITH: Okay. Also, I know that you have had a lot of interest and a great understanding of the bio-safety protocols; and we, obviously, have got Terri Dunnahay, who has been very involved in that.

Just from your organization's perspective, is there any other comment that you want to make related to that, implications of that for us that you haven't already mentioned?

MR. O'CONNOR: In respect to the bio-safety protocol, or just in general?

MS. SMITH: Yes.

MR. O'CONNOR: No, I think Terri has been doing a really good job, at least in keeping us posted. I guess she probably is over there and may be on her way back now from that. We were very disappointed with some of the outcomes of it, particularly on the documentation side, the 18 2A side of the bio-safety protocol.

That is now, I guess, going to mandate identification of the crops that may be in commodity shipments, which is potentially very problematic for us. So that was kind of a disappointing outcome.

But from the feedback that we got from our industry colleagues who were over there, it looked

like that boat had left the dock by the time we got there. Because even though the U.S. strongly opposed it, as well as Canada and Australia and even Brazil, and the industry, of course, did also, it still got adopted by the parties.

MR. TURNER: Meaning that we can't use the "may contain" clauses --

MR. O'CONNOR: You'll use the "may contain" clause and then you will identify the specific elements that are in that cargo. Go figure.

MS. SMITH: You use the "may contain" clause and then identify them?

MR. O'CONNOR: Right. Not only would you identify, I forget the exact -- it is a common name, a scientific name, the transformation events and there is something -- the unique identifier.

MS. SMITH: So, in those words, anything that we have approved already that is commercially grown would have to be identified on that label?

MR. O'CONNOR: Right. That is correct.

For example, again, we have this horrible example of Starlink. Unfortunately, that would probably have to be on the label even though it is moving towards a zero number. Basically, a background number.

The same thing with crops that perhaps have gone out of commercial production. Maybe a GA 21, for example, has been replaced by a NK 603. Maybe that hasn't been proved some place, but NK 603 has. Then you can have both of those on the label, so it is going to present, I think, some commercial challenges for us if we understand this correctly.

We will have to get back and get a sort of debrief from those who were over there who understand it, but that is our initial read.

MR. WACH: Is there a detection limit set?

MR. O'CONNOR: No, zero.

MS. SMITH: Zero, period.

MR. TURNER: I thought they would be pushing us in the other direction rather than listing everything that could be there that they would want to know specifically based on some limits, what is likely to be there or based on testing because it seems like this isn't very helpful.

MR. O'CONNOR: Frankly, I totally agree with you, John, that actually some of our initial advice to the parties to the protocol was exactly that. If you have a "may contain" label, it just lets everything -- what information do you have?

MS. SMITH: Yes.

MR. O'CONNOR: But even if it was listed, and even if you went in the other direction and said: Well, just list those that are specifically there, then you get into a testing issue and you have to actually test it for everything that may be in the marketplace and that becomes expensive.

MR. TURNER: Right.

MR. O'CONNOR: So whichever way you go, it is a problem.

MS. SMITH: Other questions now that we all feel really good?

(Laughter)

MR. O'CONNOR: Yes, well --

MS. SMITH: While picking ourselves up off the floor, I go along with you.

MR. O'CONNOR: I certainly appreciate, first of all, the opportunity to come today; and I know that you guys have been working very hard to improve your regulations of bio-tech crops, even though truly responsive to some of our concerns, and we much appreciate that.

It is a challenging issue for all of us. I think, to the extent that we can all work together on transparency, as you mentioned, and being sensitive as to how these are perceived in the overseas markets and

so, is very welcome from our side of the street.

MS. SMITH: Great. Well, thank you. We appreciate your willingness to work with us and your continuing dialogue with us. We look forward to continuing that as we move forward with the regulations.

MR. O'CONNOR: We will get some remarks back to you.

MS. SMITH: Great.

MR. O'CONNOR: This has been very helpful to better understanding, so that I can explain it to the guys when I get back at the next committee meeting.

MS. SMITH: When you go back and explain it and you can't remember what it was anymore, we will be happy to help you.

MR. O'CONNOR: That's right. Just as long as they don't expect me to pronounce that one thing.

MR. TURNER: The arabidopsis?

MS. SMITH: Thank you.

MR. O'CONNOR: Thank you.

(Whereupon, at 4:08 p.m., the meeting in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

CASE TITLE: STAKEHOLDERS MEETING WITH
NATIONAL GRAIN and FEED ASSOCIATION

HEARING DATE: February 27, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 27, 2004

Renee Miskell

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